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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

<b>IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION</b>	<b>MDL No. 2875</b>
<b>THIS DOCUMENT RELATES TO ALL CASES</b>	<b>HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)</b>  <b>Redacted Version</b>

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**PLAINTIFFS' REPLY MEMORANDUM IN FURTHER SUPPORT OF  
DAUBERT MOTION TO PRECLUDE OPINIONS OF DEFENSE EXPERT  
TIMOTHY E. KOSTY**

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## **I. INTRODUCTION**

In their *Daubert* motion to preclude Mr. Kosty's opinions (ECF 2299), Plaintiffs explained how Mr. Kosty seeks to re-offer some of the same opinions this Court precluded at class certification due to unreliability and lack of qualifications.

Those are (i) [REDACTED]

[REDACTED] Nothing changed between Mr. Kosty's class report and this Court's preclusion of the foregoing opinions, and Mr. Kosty's new liability report. He lacked reliability and qualifications then, and still does.

Defendants' Response (ECF 2326) does not dispute that this Court previously precluded the exact same, unreliable opinions now at issue here. Nor do Defendants dispute this Court's prior holding that Mr. Kosty is unqualified to opine on [REDACTED]

[REDACTED].

Instead, Defendants pivot. They [REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

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[REDACTED]

Even if this Court did not already find Mr. Kosty unqualified to offer the same unreliable, speculative opinions he attempts to re-offer now, a fresh *Daubert* analysis shows that he remains unqualified, and that his challenged opinions remain unreliable and unhelpful.

## II. ARGUMENT

### A. Mr. Kosty's Economics/Damages Opinions Should Be Precluded Again

Defendants do not dispute that this Court already precluded Mr. Kosty's economics/damages opinions at the class certification stage because he lacked appropriate qualifications and his opinions were the product of unreliable methods. *See* Pls.' Mem. at 6-7 (summarizing prior ruling). In his new liability report, Mr. Kosty [REDACTED]. *Id.* at 7-8.

Defendants try to salvage Mr. Kosty's rehashed economics/damages opinions by [REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Defendants cannot trojan-horse Mr. Kosty's previously precluded economics/damages opinions [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] These opinions remain unreliable given he "lacks scientifically reliable methodology and/or necessary expert qualifications." 2/8/23 Op. (ECF 2261) at 79-80.

Equally important, Mr. Kosty lacks any reliable method or experience to substantiate his speculative view [REDACTED]

[REDACTED]

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[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Mr. Kosty's personal, uninformed, and nebulous views, without more, do not pass muster. *See, e.g., Scott v. Chipotle Mexican Grill, Inc.*, 315 F.R.D. 33, 44 (S.D.N.Y. 2016) ("At a minimum, however, rebuttal experts must meet *Daubert's* threshold standards regarding the qualifications of the expert, sufficiency of the data, reliability of the methodology, and relevance of the testimony."); *Cospelich v. Hurst Boiler & Welding Co., Inc.*, 08CV46-LG-JMR, 2009 WL 8599064, at \*2 (S.D. Miss. July 7, 2009) (excluding rebuttal expert who did not employ reliable methodology or explain how his experience informed his analysis); *Rondor Music Int'l Inc. v. TVT Records LLC*, CV 05-2909-JTL, 2006 WL 5105272, at \*3 (C.D. Cal. Aug. 21, 2006) (excluding rebuttal expert unable to articulate a specific process or methodology by which she reached her conclusions).

**B. Mr. Kosty's Opinions on What TPPs Rely on for Reimbursement Decisions Should Be Preluded Again**

As with their attempt to recast and resuscitate Mr. Kosty's economics/damages opinions, Defendants also attempt to recast and resuscitate his

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opinions about what TPPs rely on in making drug reimbursement decisions. This attempt, too, should be rejected.

Plaintiff's opening memorandum established that [REDACTED]

[REDACTED]

[REDACTED] which the Court previously precluded at the class certification stage, *see* 2/8/23 Op. (ECF 2261) at 80. Specifically, the Court previously noted at page 79 of its opinion that Mr. Kosty's opinions about TPPs' reimbursement decisions and responses to Dr. Panagos' opinions appeared at pages 49-99 of his class certification report:

2) From pp: 49-99, his Report refutes three of plaintiffs' class certification experts' reports: Laura Craft's Report on an acceptable methodology for identifying proposed economic class member; and on the amount paid for the VCDs; Dr. Rena Conti's Report on valuation of economic losses by consumers and TPPs; and Dr. Kaliopi Panagos's Report on the use of the Orange Book by the drug industry.

The Court proceeded to preclude all of these opinions:



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In addition, Mr. Kosty states that Dr. Panagos is incorrect when she asserts that the FDA's Orange Book acts as a warranty to consumers and their insurers. Dr. Kosty asserts without more that the drug industry would not have regarded the Orange Book as a warranty that generic drugs are the equivalent of all of the RLD's biological and chemical features. Regardless of the correctness of Dr. Panagos' opinion about the drug industry's perception of the Orange Book as a warranty of the substantial equivalence of generic drugs, Mr. Kosty's refutation of the drug industry's "perceptions" needed more reliable support than his mere disagreement.

In sum, Mr. Kosty's Report lacks scientifically reliable methodology and/or necessary expert qualifications in refuting the Class Certification Reports of plaintiffs' experts, Laura Craft, Dr. Rena Conti, and of Dr. Kaliopi Panagos.

Accordingly, Mr. Kosty's opinions in pages 49-99 in his Report have been precluded. His discussion on the workings of the U.S. pharmaceutical industry in pages 15-48 of his Report has been considered

Thus, Defendants are mistaken that the Court previously did not exclude all of Mr. Kosty's opinions regarding TPPs' reimbursement decisions. *See* Defs.' Resp. at 8-9. It did.

Moreover, as Plaintiffs' opening memorandum explained (*see* Pls.' Mem. at 12-14), [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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### **III. CONCLUSION**

For the foregoing reasons, as well as those set forth in Plaintiffs' opening memorandum, Mr. Kosty's economics/damages opinions, and opinions on what TPPs might rely on when making drug reimbursement decisions, should be precluded.

Respectfully,

ON BEHALF OF PLAINTIFFS

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Dated: April 25, 2023

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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on April 25, 2023, a true and correct redacted copy of the foregoing was filed and served via the court's CM/ECF system, and an unredacted version was served on the court and the Defense Executive Committee via email.

/s/ David J. Stanoch  
David J. Stanoch